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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,754	10/10/2001	Eric Lietz	22477-708	8731

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EXAMINER	
CHAKRABARTI, ARUN K	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 01/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/975,754	Lietz
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *10/10/01, 9/6/02, 9/11/02* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-20* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *10, 11*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

2. Claims 1-3, 6-12, and 15-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 14, and 16-25 of U.S. Patent No. 6,319,694 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 13, 14, and 16-25 of U.S. Patent No. 6,319,694 B1 discloses the same method of instant claims 1-3, 6-12, and 15-20 of producing a library of mutagenized polynucleotides from a target sequence using two sets of primers, each set having a fixed sequence and a random sequence. Instant claims 1-3, 6-12, and 15-20 recite the word "unknown" instead of "random" as described in the U.S. Patent No. 6,319,694 B1. This change of phrase does not make the claims patentably distinct because the phrases "unknown" and

"random" are synonymous as described and explained in the specification of the instant application on page 9, lines 4-6.

3. Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 14, and 16-25 of U.S. Patent No 6,319,694 B1. in view of Huston et al. (U.S. Patent 5,877,305) (March 2, 1999).

U.S. Patent No 6,319,694 B1 discloses the claims 1-3, 6-12, and 15-20 as described above.

U.S. Patent No 6,319,694 B1 does not teach the method wherein the target sequence has a sequence which is the CDR of an antibody and which encodes a single-chain antibody having specific conserved amino acid residues.

Huston et al. teach the method wherein the target sequence has a sequence which is the CDR of an antibody and which encodes a single-chain antibody having specific conserved amino acid residues (Column 17, lines 8-47).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method wherein the target sequence has a sequence which is the CDR of an antibody and which encodes a single-chain antibody having specific conserved amino acid residues of Huston et al. with the method of producing a library of mutagenized polynucleotides from a target sequence using two sets of primers of U.S. Patent No 6,319,694 B1, since Huston et al. states, "The invention also embodies a humanized single-chain Fv, i.e., containing human framework sequences and CDR sequences which specify c-erb-2

binding, e.g., like the CDRs of the 520C9 antibody. The humanized Fv is thus capable of binding c-erb-2 while eliciting little or no immune response when administered to a patient (Column 17, lines 8-13) ". An ordinary artisan would have been motivated by these express statements of Huston et al to substitute and combine the method wherein the target sequence has a a sequence which is the CDR of an antibody and which encodes a single-chain antibody having specific conserved amino acid residues of Huston et al. with the method of producing a library of mutagenized polynucleotides from a target sequence using two sets of primers of U.S. Patent No 6,319,694 B1, in order to achieve the express advantages of the humanized Fv, as noted by Huston et al , which is capable of binding c-erb-2 while eliciting little or no immune response when administered to a patient.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

January 10, 2003

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600